EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C. R. BARD, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION — **MDL NO.: 2187**

THIS DOCUMENT RELATES TO:

CAROLYN JONES — **2:11-cv-00114**

MOTION TO AMEND INTERLOCUTORY ORDER
(Entering Partial Summary Judgment in Favor of Defendant on Causation Element of "Failure to Warn" Theory of Liability)

COMES NOW the Plaintiff, CAROLYN JONES, by counsel, and requests this Honorable Court to reconsider and amend its interlocutory ruling in the **Memorandum Opinion and Order** [Docket 288] entered June 4, 2013, which granted partial summary judgment in favor of the Defendant on the issue of "whether the inadequate warning proximately caused the alleged injury" (p. 10) pursuant to Miss. Code Ann. § 11-1-63(a)(iii). Plaintiff respectfully submits the Court's ruling is legally and factually in error[1] and requests reconsideration pursuant to Rule 54(b) of the Federal Rules of Civil Procedure.[2]

[1] "A decision is clearly erroneous when, after reviewing the entire record, a court is left with the definite and firm conviction that a mistake has been committed. A decision is contrary to law when it fails to apply or misapplies relevant statutes, case law or rules of procedure." *McCornack v. Actavis Totowa*, LLC, 2011 WL 2836318 (S.D.W.Va. 2011).

[2] Under Rule 54(b), "any order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." Unlike a motion to vacate a final judgment, which is governed by Rule 59(e) or Rule 60(b), the Court retains the discretion to modify a prior interlocutory order under the "as justice requires" standard. See *In re Digitek Prods. Liab. Litig.*, 2010 WL 5396377, *1 n. 2 (S.D.W.Va. 2010) ("Both sides are mistaken that Federal Rule of Civil Procedure 59(e) governs reconsideration here. See*Bragg v. Robertson*, 183 F.R.D. 494, 495–96 (S.D.W.Va.1998) ("[T]he Court retains power to amend interlocutory orders to achieve complete justice. 'An interlocutory order is subject to reconsideration at any time prior to entry of a final judgment.'") (quoting Fayetteville Investors v. Commercial Builders, Inc., 936 F.2d 1462, 1469 (4th Cir.1991)."). See also *Hamilton v. Geithner*, 616

Plaintiff alleges a "failure to warn/instruct" under Mississippi law. Miss. Code Ann. § 11-1-63[3]; see also *Wyeth Laboratories, Inc. v. Fortenberry*, 530 So.2d 688, 692 (Miss. 1988) ("An adequate warning is one reasonable under the circumstances."). This Honorable Court ruled there is a genuine issue of material fact as to whether the warnings provided by Bard were adequate under the circumstances. (**Memorandum Opinion and Order** at p. 10). However, the Court ruled as a matter of law that Plaintiff cannot meet her burden of proof of causation because the physician "simply never read the IFU" and, therefore, "additional or different warnings would not have prevented him from implanting the Avaulta product into Ms. Jones." (**Memorandum Opinion and Order** at p. 12).

The Court's ruling is clearly erroneous because it overlooks causation evidence in the record, including but not limited to, disclosures made by Bard to Dr. Williams during a 2-day Bard training program. The implanting surgeon, Dr. David Williams, testified that he attended the Bard training course prior to the Jones surgery. (Williams depo., filed of record in support of Bard's summary judgment motion, pp. 12-13). The training included a didactic seminar (p. 13), live speakers (p. 14) and physician training in a cadaver lab (p. 14). Dr. Williams' testimony,

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F. Supp. 2d 49, 54 (D.D.C. 2009) ("[T]he standard of review for interlocutory decisions differs from the standards applied to final judgments….In particular, reconsideration of an interlocutory decision is available under the standard, 'as justice requires.'").

[3]"An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product." Miss. Code Ann. § 11-1-63(a)(ii).

cited in the response brief, relates to information he did, or did not, receive during the "Bard training session."[4] Specifically, Dr. Williams was asked:

> Q: All right. I'm going to ask you a series of questions and just ask you if you were provided this type of information at either the Bard training session or through any additional Bard information and just let me know whether you did or not and whether it would have been important to you to have had this type of information.
>
> A: Yes, sir.

(Williams Depo. pp. 20-21). Immediately following this question, Dr. Williams was asked about information, or the lack thereof, he received during the Bard training session relating to pore size (pp. 21-22), degradation (p. 22), weakening of the mesh during the manufacturing process (p. 22), elasticity (p. 23), deformation (p. 23), structural stability (p. 24), inflammatory response and scar plating (p. 24), porcine (pp. 24-26), pre-market studies (pp. 26-27), post-market studies (p. 27), reports of adverse events (p. 28), shrinkage (pp. 28-29), removal of the mesh following complications (pp. 29-30) and more.

Dr. Williams testified that he relied upon this information to exercise his medical judgment under the learned intermediary doctrine:

> Q: I want to ask you detailed or follow-up questions on your – the risks and benefit analysis that you conduct and discuss with your patients like Ms. Jones. As far as doing a risk/benefit analysis, is that something that you would have received instruction and training on starting with your residency and internship and your medical education?
>
> A: Yes, all part of the process. […]
>
> **Q: And just want to go over the sources of information that you would have when considering risks and benefits of products like vaginal mesh products like the Avaulta and Align, that you have the training that you talked about attending from manufacturers like Bard?**
>
> A: Uh-huh (indicating yes).

[4]The deposition transcript mentions the scope of information communicated during the Bard training sessions no less than ten (10) separate times: (Williams depo., pp. 20-21, 29-30, 35, 88, 94-95, 97, 101-02, 110, 113-15).

Q: Yes?

A: Yes, ma'am.

Q: And then your education, including all the continuing [medical] education? […]

A: Yes.

Q: And do you sometimes look on the internet for information as far as studies or articles that are available on the internet?

A: I don't do a lot on the internet. I do through our professional journals. I'll look over the topics and see what interests.

Q: And then do you draw on all those things in doing your risk/benefit analysis with patients?

A: Yes.

Williams Depo. at pp. 101-102.

Dr. Williams testified fourteen (14) times that he would have changed his mind about performing the procedure if he had been informed about certain risks during the training session: (p. 22, lines 4-7) (p. 22, lines 14-16) (p. 22, lines 22-25) (p. 23, lines 11-13) (p. 23, lines 22-24) (p. 24, lines 16-17) (p. 26, lines 10-12) (p. 26 lines 20-22) (p. 27, lines 19-21) (p. 29, lines 1-5) (p. 40, lines 3-5) (p. 42, lines 18-20) (p. 44, line 1) (p. 115, lines 20-23). Plaintiff should be entitled to present evidence to the jury that the information provided to Dr. Williams during the training program was wrong, inaccurate, incomplete, inadequate and/or misleading.

The record is clear that Bard intended for the implanting surgeons to rely on information from the Bard training sessions. Mr. Gary Teague is the Bard director of physician training and was deposed on August 10, 2012. A copy of volume II of his transcript is attached hereto as **Exhibit 1**. Mr. Teague testified as follows:

a. Bard would pay for "airfare, hotel and any incidental expenses" for the surgeons to attend the training sessions on the Avaulta products. (Teague Depo. at p. 269);

b. "Our job was to teach these physicians" (Teague Depo. at p. 272) and educate the physicians regarding the "characteristics of the implant and the technique that was utilized to implant it." (Teague Depo. at p. 273);

c. Doctors were informed during the training session: "this is the product, this is what it's supposed to do and this is why it's supposed to do that." (Teague Depo. at p. 273);

d. The materials used during the training sessions were approved through the Bard compliance department. (Teague Depo. at p. 280);

e. Subject matters addressed during the Bard training seminar included complications (p. 273), complication rates (pp. 273-74), adverse events (p. 274), elasticity (p. 279, 282-84), pore size (p. 286), shrinkage (p. 287)

f. Subject matters not addressed during the Bard training seminar included degradation (p. 285), the difficult of removing the mesh (p. 287),

Plaintiff respectfully submits that the duty to warn under Mississippi is broad: ***an adequate warning is one reasonable under the circumstance***s. Cause-in-fact should be equally as broad and include disclosures made during the Bard training session; not just the IFU. Plaintiff should be entitled to present evidence to the jury that the information provided during the Bard training sessions were wrong, inaccurate, incomplete, inadequate and/or misleading.

Plaintiff respectfully submits there is no precedent under Mississippi law limiting the scope of the duty to warn to the IFU. Rather, the adequacy of a warning is one reasonable under the circumstances. The Mississippi Supreme Court has implicitly rejected a *per se* rule in the context of pharmaceutical litigation when it noted, in *dicta*, that a product insert "***may be sufficient for the warning to be adequate as a matter of law***." *Wyeth Laboratories, Inc. v. Fortenberry*, 530 So.2d at 692 -693 (emphasis added). Plaintiff argues the Court erroneously

reached the legal conclusion that the IFU ***shall*** be sufficient as a matter of law without due consideration of the facts in the matter *sub judice*.

For instance, the Court cited *Porterfield v. Ethicon, Inc.*, 183 F.3d 464 (5th Cir.1999) for the proposition that there is "no evidence of causation where the surgeon failed to read the package insert or company literature." (**Memorandum Opinion and Order** at p. 12). In *Porterfield*, the Fifth Circuit considered whether the testimony of the implanting physician satisfied the burden of proof for causation by reciting the following facts:

> Porterfield has failed to present evidence that the failure to warn was a producing cause of her injury. In this case, Dr. Mimari, the surgeon who performed Porterfield's hernia surgery using the mesh, testified that at no time prior to Porterfield's surgery had he read Ethicon's package insert or any other Ethicon literature. Instead, Mimari relied on surgical literature, his own experience, and the experience of his colleagues in weighing the risks and benefits of surgery with the mesh. Mimari also testified that he was aware of the risks of infection, adhesion, and immune response. Importantly, Mimari testified that the use of mesh outweighed the possible risks because without the mesh, the likelihood of successfully repairing the hernia would have been diminished. Because Porterfield's surgeon was aware of the possible risks of using the mesh but decided to use it anyway, the inadequate warning was not a producing cause of Porterfield's injury.

Porterfield v. Ethicon, Inc., 183 F.3d at 468. Importantly, the Fifth Circuit did not hold the implanting surgeon must read the IFU in order for the Plaintiff to sustain her burden of proof on causation. Rather, the Fifth Circuit analyzed the facts of the *Porterfield* case to reach its conclusion.

The facts in *Porterfield* are clearly distinguishable from this matter. In *Porterfield*, there was no evidence that the implanting surgeon had received **any** warnings or instructions from the medical device manufacturer. The IFU was the only opportunity for Ethicon to communicate adequate warnings and instructions to the implanting surgeon. In the matter *sub judice*, Dr. Williams testified that he received: direct training from Bard regarding the Avaulta product

(Williams Depo. pp. 20-21, 29-30, 35, 88, 94-95, 97, 101-102, 110, 113-115); DVDs from Bard (Williams Depo. pp. 20, 88); brochures relating to the Avaulta products (Williams Depo. p. 88); and was accompanied by a Bard sales representative in the operation room "almost every time that I can remember (Williams Depo. pp. 18-19). Plaintiff submits that Bard owed a duty to adequately warn/instruct Dr. Williams during the Bard training session as well as provide updated information during the life cycle of the product during its other interactions with the implanting surgeon.

In addition, and decisively, the implanting surgeon in *Porterfield* testified that he was aware of the risks of the hernia mesh and "decided to use it anyway." In the matter *sub judice*, Dr. Williams testified he was unaware of certain risks, he was misinformed about certain aspects related to the proper installation of the product (i.e, Dr. Williams was informed by Bard the mesh "shrinks" but not to the extent of 30-40%)[5], and that this information would have changed his mind regarding use of the product.

The Court also relies on a *Latiolais v. Merck & Co.*, 2007 WL 5861354 (C.D.Cal.2007) in its memorandum opinion. In *Latiolais*, a California district court ruled "that because Decedent's doctor admits that the product insert, including the warnings, played no role in his decision to prescribe Zocor, and because Plaintiff has presented no evidence that the doctor would have changed his decision to prescribe Zocor even had adequate warnings been provided, Plaintiff cannot show that a failure to warn caused her husband's suicide." *Latiolais v. Merck & Co., Inc.*, 2007 WL 5861354 at *1.

[5] It should be noted that Bard marketed and sold Avaulta as a kit and procedure. Proper installation of the mesh was taught during the Bard training session and relied upon technical information such as shrinkage to avoid asymmetrical forces on the arms of the mesh.

Again, the *Latiolais* Court did not adopt a *per se* rule that a physician must read the product insert in order for the plaintiff to sustain her causation burden of proof. Rather, the *Latiolais* Court analyzed the facts of the case and determined:

a. The physician's decision to prescript the medication was "guided solely by two factors, or sources of information" including clinical experience and a medical literature;

b. The physician could not recall receiving any information from Merck;

c. The physician could not recall any interaction with a Merck representative;

d. The physician could not recall being influenced by any information from Merck;

e. The physician could not recall reading the package insert but stated conclusively that the inserts played no role in his decision to prescribe the medication;

f. The physician testified that he still would have prescribed the medication even if he had read the product insert.

The facts in *Latiolais* are distinguishable from the matter *sub judice*. Dr. Williams testified that his sources of information relating to Avaulta mesh included the Bard training session, Bard written materials, DVDs and brochures, interactions with a Bard sales representative during almost every procedure, and, importantly testimony that he would not have used the Bard product on Plaintiff Jones if certain information had been disclosed.

If this Court determines the duty to warn includes representations made during the Bard training session, or the duty to warn extends beyond the IFU under these circumstances, then Plaintiff has met her burden of proof on causality. Conversely, if the Court determines the duty to warn is limited solely to the scope of the IFU, thereby upholding partial summary judgment in favor of Bard, then Plaintiff respectfully requests the entry of a Rule 54(b) order noting there is "no just reason for delay" and permit an immediate appeal.

An immediate appeal is necessary because of the national consequences of such a ruling. In essence, the Court's ruling creates an automatic dismissal of every "use defect" claim in the MDL based upon the singular fact of whether the implanting surgeon read the IFU. The Court's ruling essentially limits the duty to warn to the IFU. Bard argues that it is entitled to summary judgment on a failure to warn claim, irrespective of any other form of disclosure, *if* the implanting physician testifies he/she did not read the IFU.

Plaintiff Jones submits the duty to warn under Mississippi law is broader than the IFU and is dependent upon the facts of the case. Plaintiff petitions this Court to reconsider its ruling and set forth its findings of fact and conclusions of law specifically pertaining to the following issue: ***whether the IFU is the sole source of information upon which an implanting surgeon must rely for the Plaintiff to sustain her burden of proof on causation***.

WHEREFORE, Plaintiffs, CAROLYN JONES, by counsel, respectfully requests this Honorable Court to amend its **Memorandum Opinion and Order** [Docket 288] entered June 4, 2013, and permit the presentation of evidence of "failure to warn/instruct" to the jury in accordance with Mississippi law. If the Court declines, Plaintiff respectfully requests the entry of a Rule 54(b) order to permit an immediate appeal.

Date: June 10, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on June 10, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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